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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

ALLERGAN PLC, ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMA, AND ADAMAS PHARMACEUTICALS, INC.,

Defendants.

Case No.: 3:18-cv-3018-JCS

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF:

1. **THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729–3733; AND**

2. **THE FALSE CLAIMS ACTS OF THE PLAINTIFF STATES, COMMONWEALTHS, AND THE DISTRICT OF COLUMBIA**

***QUI TAM* ACTION FILED *IN CAMERA* AND UNDER SEAL**

DO NOT PLACE IN PRESS BOX
DO NOT ENTER ON PACER

JURY TRIAL DEMANDED

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Plaintiff-Relator Zachary Silbersher ("Relator"), through his attorneys the Joseph Saveri Law Firm, Inc., on behalf of the United States of America; the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington; the Commonwealths of Massachusetts and Virginia; and the District of Columbia (the foregoing states, commonwealths and the District of Columbia collectively, "the Plaintiff States"), for his First Amended Complaint against defendants Allergan PLC, Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. (collectively, "Allergan"); and Adamas Pharma, and Adamas Pharmaceuticals, Inc. (collectively, "Adamas") ("Allergan" and "Adamas" collectively, "Defendants"), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. Defendants manufacture, sell and distribute in the United States Namenda XR® and Namzaric®, which are extended release medications prescribed to treat dementia related to Alzheimer's disease. Defendants maintained the exclusive rights to manufacture, sell, and distribute these drugs in part by listing several patents relating to Namenda XR® and Namzaric® in the United States Food and Drug Administration's ("FDA's") database of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Nearly all of these patents were acquired through fraudulent means.

2. The patents fall into three categories. The first category, known as the "Went Patents," is a set of eleven related patents that are directed to an extended release formulation of memantine hydrochloride. Defendants were aware of a study that showed the extended release formulation described in the Went Patents caused more side effects than the previously approved immediate release formulation. Defendants knew that if they accurately disclosed the study's findings to the United States Patent Office (the "Patent Office"), the Patent Office would not have issued the Went Patents. Defendants therefore misrepresented the findings of the study to the Patent Office, falsely stating that the study showed no side effects for the extended release formulation.

Relator is informed and believes Defendants knowingly and intentionally misrepresented the findings of the study to induce the Patent Office to allow the Went Patents.

3. The second category is United States Patent No. 8,039,009 ("the '009 Patent"), which claims once-daily administration of memantine hydrochloride for treatment of Alzheimer's disease. Defendants were aware of a patent in the prior art that taught the same "once-daily" limitation claimed in the '009 Patent. However, Defendants did not inform the Patent Office of the prior art teachings when they amended their patent application to claim a once-daily formulation of the drug. Relator is informed and believes Defendants knowingly and intentionally withheld information about the prior patent because such disclosure would have caused the Patent Office to reject the '009 Patent.

4. The third category is United States Patent No. 5,061,703 ("the '703 Patent"), which teaches administration of memantine hydrochloride to treat Alzheimer's disease. Defendants only asserted the '703 Patent against two would-be generic manufacturers of Namenda XR® (and none of the other potential generic manufacturers of the drug). In any event, the '703 patent expired on April 11, 2015, so it has not blocked generic entry for any generic manufacturer since at least that date.

5. On information and belief, Defendants knowingly and intentionally made false statements to, and withheld material information from, the Patent Office to obtain the Went Patents and the '009 Patent. Defendants asserted these fraudulently-acquired patents to prevent generic manufacturers from entering the market. Having wrongfully excluded generic competition, Defendants were able to and did charge monopoly prices for these drugs.

6. Namenda XR® and Namzaric® are paid for, reimbursed for, or purchased by Medicare, Medicaid, and various federal and state agencies that provide or pay for health services. Each claim for payment or reimbursement for Namenda XR® or Namzaric® submitted to the Federal Government or the Plaintiff States was a false claim, actionable under the federal False Claims Act (the "FCA") and the false claims acts of the Plaintiff States (each, a "State FCA"), because Defendants gave the federal government and the Plaintiff States multiple express and implied assurances that the prices Defendants were charging for Namenda XR® and Namzaric® were "fair and reasonable." They were not. The federal government and the Plaintiff States materially relied on

Defendants' false and misleading statements and certifications when paying or reimbursing claims for Namenda XR® and Namzaric®. Defendants knowingly and intentionally caused each claim to be submitted for an artificially high price that Defendants charged as a result of their fraudulently-obtained patent.

7. Additionally, each claim for reimbursement or payment for a prescription of Namenda XR® or Namzaric® that would have been filled by a generic alternative had Defendants not unlawfully excluded such competitors from entering the market also constituted a False Claim.

8. As a result of Defendants' fraudulent activities, the Federal Government and the Plaintiff States have overpaid for Namenda XR® and Namzaric® by potentially more than $2.5 billion dollars. Under the federal FCA and most of the State FCAs, the damages from such overpayment are trebled. In addition, statutory penalties can be assessed for each false claim. Medicare covered 5,408,646 prescriptions for Namenda XR® in 2014 and 2015 alone, each a false claim. The Plaintiff States are also entitled to damages and penalties under their respective statutes.

This is an action to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States arising from Defendants' violations of the federal FCA, 31 U.S.C. §§ 3729–3733 (the "Federal FCA"), and the State FCAs in connection with Defendants' sales of Namenda XR® and Namzaric®.

II. PARTIES

9. The Relator, Zachary Silbersher, is a citizen of the State of New York. Relator's profession focuses on investigating invalid pharmaceutical patents that brand manufacturers use to protect their drugs from price competition. Through his independent investigation, Relator has uncovered non-public information supporting the claims set forth herein. The Relator's independent research and investigation has generated information that is independent of, and materially adds to, any publicly-disclosed allegations and transactions.

10. Relator is an "original source" of information within the meaning of 31 U.S.C. § 3730(e)(4)(B) and all applicable State FCAs. Relator has voluntarily provided the information on which the allegations or transactions alleged herein are based to the Federal Government and the Plaintiff States before filing this action.

11. Relator seeks to recover all available damages, civil penalties, and other relief for federal and state-law violations alleged herein. In particular, Relator sues to recover on behalf of the United States Government and its various agencies administering federally funded health care programs, including, without limitation, Medicare; Medicaid; CHIP; the Indian Health Service; the Federal Bureau of Prisons' Health Services Division; the Veterans Health Administration; the Military Health System; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Defense Health Agency / TRICARE; and the Coast Guard's Office of Health Services. Relator also sues to recover on behalf of the Plaintiff States and their respective agencies administering state programs for prescription drug coverage, including, without limitation, Medicaid contributions.

12. Defendant Allergan PLC is a company organized and existing under the laws of Ireland, with its principal place of business at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland.

13. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located in Parsippany, New Jersey. During most of the relevant period, Allergan's headquarters were located in Irvine, California, where it still maintains a substantial physical presence.

14. Defendant Allergan USA, Inc. is a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, NJ 07940. During most of the relevant period, Allergan's headquarters were located at 2525 Dupont Drive, Irvine, CA 92612, where it still maintains a substantial physical and administrative presence.

15. Defendant Allergan Sales, LLC is a Delaware limited liability company with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

16. Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation with its principal place of business at Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda. Allergan is the successor-in-interest to Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) and is liable for any damages to which Forest is liable.

17. Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd., are all subsidiaries or divisions of Allergan PLC. On July 1, 2014, Actavis PLC

acquired Forest laboratories, Inc. On March 17, 2015, Actavis PLC acquired Allergan, Inc. On June 15, 2015, Actavis PLC changed its name to Allergan PLC.

18. Defendant Adamas Pharma, LLC is a Delaware limited liability company having a principal place of business at 1900 Powell Street, Suite 750, Emeryville, California 94608.

19. Defendant Adamas Pharmaceuticals, Inc. is a Delaware corporation having its principal place of business at 1900 Powell Street, Suite 750, Emeryville, California 94608 (together with Adamas Pharma, LLC, "Adamas") ("Allergan" and "Adamas" collectively, "Defendants").

20. Defendants sell Namenda XR® and Namzaric® in the United States.

III. JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. §§ 3730(b)(1) and 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims.

22. Under 31 U.S.C. § 3730(e), and under the comparable provisions of the Plaintiff State statutes, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Moreover, whether or not such a disclosure had occurred, Relator would qualify as an "original source" of the information in this Complaint. Relator has independent knowledge of the information on which the allegations herein are based; such knowledge materially adds to any publicly disclosed allegations or transactions; and Relator voluntarily provided the information to the Government before filing this action and before any public disclosure of the allegations and transactions in this Complaint material to the false claims alleged herein.

23. This Court has personal jurisdiction over each of the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Moreover, each of the Defendants maintains minimum contacts with the United States. Each of the Defendants can be found in this District. Each of the Defendants transacts business in this District. And each of the Defendants has presented or has caused to be presented (and continues to present or cause to be presented) false or fraudulent claims for payment in this District.

24. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), 28 U.S.C. 1395(a), and 31 U.S.C. § 3732(a), because Defendants can be found in and transact business in this District. At all times relevant to this Complaint, each of the Defendants regularly conducted substantial business within this District and made significant sales within this District. Moreover, numerous acts violating 31 U.S.C. §§ 3729–3733 occurred in this District, and a substantial part of the events giving rise to the claims alleged herein occurred here.

25. Many of the acts underlying the false claims allegations herein occurred in this District.

IV. FEDERAL AND STATE-FUNDED HEALTH CARE PROGRAMS

26. Government-funded health care programs cover medical services and prescriptions for one-third of the United States population.

a. Medicare

27. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. The Medicare program is administered through the Centers for Medicare & Medicaid Services ("CMS") a federal agency within the United States Department of Health and Human Services ("DHHS").

28. The Medicare program has four parts: Part A, Part B, Part C, and Part D. Medicare Part A ("Part A"), the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans. Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

29. Medicare provides benefits for patients being treated with Namenda XR® and Namzaric® under Part D.

b. Medicaid

30. Medicaid is jointly administered by the United States and each of the separate states, including the Plaintiff States.

31. Individual state Medicaid programs are administered by each individual state, subject to oversight by the United States in accordance with statutes and regulations promulgated by the United States and the Secretary of the DHHS. Pursuant to these statutes and regulations, the United States provides financial assistance to each of the state Medicaid programs by providing each state with financing equal to at least 50% of the costs incurred by the state Medicaid programs. In some instances, the United States provides financing equal to as much as 75% of program costs incurred, including the costs incurred for reimbursing providers for dispensing prescription drug products (such as Namenda XR® and Namzaric®) to Medicaid beneficiaries.

32. Each state Medicaid program obtains federal financial assistance by submitting quarterly claims to the United States for costs incurred administering the state Medicaid programs.

c. Other Government-Funded Health Programs

33. The other major government-funded health programs—including CHIP; the Indian Health Service; the Federal Bureau of Prisons' Health Services Division; the Veterans Health Administration; the Military Health System; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Defense Health Agency / TRICARE; and the Coast Guard's Office of Health Services—purchase significant amounts of Namenda XR® and Namzaric® for their covered patients.

V. THE REGULATORY STRUCTURE THAT DEFENDANTS MANIPULATED TO BLOCK GENERIC COMPETITORS TO NAMENDA XR®

a. The Regulatory Structure for Approval of Generic Drugs

i. The United States Federal Food, Drug and Cosmetic Act

34. Under the United States Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer must obtain FDA approval to sell a new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301–392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug. In addition, an NDA must identify any patent that allegedly claims either the approved drug or approved methods of use of the drug that could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the approved brand drug prior to the expiration of the listed patent. 21 U.S.C. § 355(a), (b). When the FDA approves an NDA, it

publishes the patents identified by the brand manufacturer in a database called "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

35. The FDA relies completely on a brand manufacturer's truthfulness about patent validity and applicability, because it does not have the resources or authority to verify that a manufacturer's patents were not procured through fraud or are otherwise invalid. In listing patents in the Orange Book, the FDA merely performs a ministerial act. Therefore, pharmaceutical companies that list patents in the Orange Book that they claim protect a particular drug have a duty to list only those patents that they believe in good faith restrict generic entry.

ii. The Hatch-Waxman Amendments

36. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. (1984). A generic manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. An ANDA applicant must demonstrate that the proposed generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. *See generally* 21 U.S.C. § 355(j) *et seq.* To do so, an applicant must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug. Additionally, an applicant must prove that the generic drug is absorbed at the same rate and to the same extent as the brand drug.

37. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration, dosage and form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug is absorbed at

the site of drug action to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical to a brand name drug in dosage, form, safety, strength, route of administration, and intended use.

38. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, allowing their substitution for the brand when a patient presents a prescription for the brand product.

39. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, thereby reducing healthcare expenses nationwide. As a result, generic drugs became an increasingly large part of prescription drug revenues and a growing threat to brand name drug profits. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 84% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine and Shifting Costs of Healthcare* 30, 51 (2014).

iii. Paragraph I, II, III, and IV Certifications

40. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications for each Orange Book-listed patent:

I. That no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

II. that the patent for the brand drug has expired (a "Paragraph II certification");

III. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

IV. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. §355(j)(2)(A)(vii).

41. Because ANDAs with Paragraph I, II, or III certifications face no potential patent challenge, FDA approval of these ANDAs is relatively expeditious.

42. However, when a generic manufacturer is forced to file a Paragraph IV certification because the Orange Book lists a drug that has not or will not expire by the time of the planned generic entry, the brand manufacturer is able trigger extensive regulatory delays that will block FDA approval of generic entry—potentially for many years. Moreover, the filing of Paragraph IV certifications and the resulting patent infringement actions delay ANDA approval by the FDA and divert resources from prompt ANDA approval and the introduction of generic alternatives into market.

43. When a generic manufacturer files a Paragraph IV certification, it must promptly provide notice to the brand manufacturer. Filing an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement regardless of the merits of the action. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months from the notification date, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product. Tentative approval means the ANDA would be ready for final approval but for the 30-month stay. As a practical matter, the initiation of a patent infringement action provides the brand manufacturer with the equivalent of an automatic 30-month injunction that prevents the generic manufacturer from releasing a competing generic product, regardless of the merits of the infringement action.

iv. United States Patent Law

44. United States patents grant the patent owner or assignee the exclusive right to exclude others from practicing the patent for a fixed period of time from the patent's priority date.

45. Under applicable patent law, an application for a patent will be rejected by the Patent Office if the invention was "patented, described in a printed publication, or in public use, on sale, or

otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102. Even if the invention was not previously disclosed as set forth in §102, a claim nevertheless is unpatentable if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103. If the Patent Office uncovers prior art that satisfies sections 102 or 103, it establishes a *prima facie* case of obviousness. To overcome a *prima facie* case of obviousness, the patent applicant has a number of options, including: (i) narrowing the invention to distinguish over the prior art; (ii) arguing the prior art does not render the claim obvious; or (iii) submitting objective evidence of secondary considerations, including unexpected results, commercial success, long-felt but unsolved need, and failure of others.

46. A patent applicant has an affirmative duty of candor and good faith when prosecuting a patent application, which includes an affirmative duty to disclose all material prior art known to the applicant at the time of the application. 37 C.F.R. § 1.56. Failing to disclose or misrepresenting information that is material to the patentability of a pending claim can subsequently render an issued patent unenforceable. 37 C.F.R. § 1.56(a) ("[N]o patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."); *see also C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, 1367 (Fed. Cir. 1998) ("Fraud in obtaining a United States patent is a classical ground of invalidity or unenforceability of the patent."). Moreover, concealing a material fact in a matter within the jurisdiction of a federal executive agency is a criminal offense punishable by fine and imprisonment. 18 U.S.C. § 1001.

b. The Economic Benefits of Blocking Generic Entry, Even When Frivolous

47. AB-rated generic drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their branded counterparts. The only material difference between generic drugs and branded drugs is their price: when multiple generic drug manufacturer competitors enter the market for a given branded drug, generic drugs cost, on average, 80%-90% lower than the branded drug prior to generic entry. Moreover, the Federal Trade Commission

(FTC) estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales.

48. When multiple generics enter the market, competition accelerates, and prices drop to their lowest levels. Competition from several generic sellers drives drug prices down toward marginal manufacturing costs. Defendants prevented this from happening with Namenda XR® and Namzaric® by applying for and obtaining the Went Patents and the '009 Patent, which would have excluded generic alternatives to Namenda XR® and Namzaric® through 2029. But for these illegally acquired patents, generics would have entered the marketplace much sooner, which would have lowered prices for generic Namenda XR® and Namzaric® by 85 to 90 percent. Indeed, Allergan's 2016 Form 10-K states that this is precisely what happened when the earlier, immediate release version of Namenda, Namenda IR®, lost its patent exclusivity: "The decrease in the US General Medicine segment revenues is primarily driven by the loss of exclusivity on Namenda® IR, which declined $541.2 million, or 97.3%, versus the prior year period."

VI. ALLEGATIONS CONCERNING DEFENDANTS' FALSE CLAIMS

a. Background

i. Namenda XR®

49. Namenda XR® is manufactured, sold, and distributed in the United States by Allergan. It was originally commercialized by Forest Laboratories, Inc. ("Forest"), in partnership with Adamas. Forest was acquired by Allergan in 2014.

50. Doctors widely prescribe Namenda XR® to treat patients with dementia related to Alzheimer's disease. Namenda XR® is a delayed-release drug whose active pharmaceutical ingredient (API) is memantine hydrochloride ("memantine"). Memantine is an N-methyl-D-aspartate (NMDA) receptor antagonist. NMDA receptors, when activated by the neurotransmitter glutamate, allow positively charged calcium ions to flow into neurons, a process that is crucial to learning and memory functions in the brain. If the NMDA receptor remains open longer than necessary, an overabundance of calcium accumulates, which eventually leads to destruction of neurons. NMDA receptor antagonists such as memantine can be used to prevent such calcium build-

up and detrimental effects. It is believed that administering memantine may help slow the degenerative process characteristic of Alzheimer's disease.

51. Namenda XR® comes in four dosages: 7 mg, 14 mg, 21 mg, or 28 mg of memantine. Defendants received FDA approval to manufacture, sell, and distribute Namenda XR® on June 21, 2010. The FDA granted Forest a three-year New Dosage Formulation exclusivity period, plus a six-month pediatric extension, which expired on or around December 21, 2013.[1] Generics have been ready to enter the market for Namenda XR® since before that date, but they were prevented from doing so by the fraudulently obtained patents asserted by Defendants, as discussed below. Two generics finally entered the market on February 21, 2018, after the Federal Circuit invalidated the asserted patents.

52. Allergan's United States net revenue for Namenda XR® was approximately $452.8 million in 2017, $627.6 million in 2016 and $759.3 in 2015. A one-month supply of Namenda XR® costs approximately $450.

ii. Namzaric®

53. Namzaric® is also manufactured, sold, and distributed in the United States by Allergan, in partnership with Adamas. Like Namenda XR®, Namzaric® is a delayed-release drug prescribed to treat patients with dementia related to Alzheimer's disease.

54. Namzaric® has two APIs: memantine hydrochloride and donepezil hydrochloride. Donepezil works by preventing the destruction of a neurotransmitter called acetylcholine. Acetylcholine facilitates memory function in the brain, among other things. Patients with Alzheimer's often exhibit a deficit of acetylcholine, possibly caused by an overabundance of a

[1] The FDA also granted Defendants M-138 exclusivity for complying with an FDA request to conduct a clinical study related to treating autism in juveniles aged 6-12 with memantine, which expired on January 3, 2018. However, because this exclusivity extension applied to juvenile uses of memantine, it did not apply to generic entry in the market for treating Alzheimer's. This is demonstrated by the fact that the FDA approved seven drug manufacturers' ANDAs for generic Namenda XR® while the M-138 exclusivity was still in effect. The labels for generic Namenda XR® bear this out. Both Amneal and Lupin's labels for their generic versions of Namenda XR® contain the following disclaimer under the heading "Pediatric Use": "Additional information describing a clinical study in which efficacy was not demonstrated in patients 6 to 12 years old is approved for Forest Laboratories' memantine HCl extended-release capsules product. However, due to Forest Laboratories' marketing exclusivity rights, this drug product is not labeled with that pediatric information."

naturally-occurring substance called acetylcholinesterase, which breaks down acetylcholine into its component chemicals. Donepezil works by inhibiting the action of acetylcholinesterase, and scientists believe that by preventing the destruction of acetylcholine in the brain, donepezil may mitigate the effects of Alzheimer's.

55. Namzaric comes in four dosages: a combination of 10 mg of donepezil with 7 mg, 14 mg, 21 mg, or 28 mg of memantine. Defendants received FDA approval for Namzaric® on December 23, 2014 at the 10/14 mg and 10/28 mg dosages, and on July 18, 2016 for the 10/7 mg and 10/21 mg dosages.[2] The FDA apparently granted no exclusivity to Namzaric®. Generic manufacturers have been ready to enter the market since at least July 13, 2015, but they have been prevented from doing so by the fraudulently-obtained patents asserted by Defendants, as discussed below. To date, no generic manufacturer has entered the market for Namzaric®.

56. Allergan's United States net revenue for Namzaric® was approximately $130.8 million in 2017, $57.5 million in 2016 and $11.2 in 2015 (Allergan launched Namzaric® on May 18, 2015). Like Namenda XR®, a one-month supply of Namzaric® costs approximately $450.

b. Defendants Obtained the Patents for Namenda XR® and Namzaric® Through Fraud.

57. Defendants listed three categories of patents for Namenda XR® and Namzaric® in the FDA's database of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Defendants asserted these patents to prevent generic manufacturers from entering the market. But as explained in detail below, all but one of the patents were acquired through fraud.

i. The Went Patents

58. The first category is a group of eleven patents known as the "Went Patents."[3] (For Namenda XR®, Defendants listed six of the Went Patents in the Orange Book (the '209, '708, '379,

[2] When referring to dosage information for Namzaric®, the first number refers to milligrams of donepezil hydrochloride, and the second number refers to milligrams of memantine hydrochloride.

[3] The Went Patents specifically include: U.S. Patent Nos. 8,058,291 ("the '291 patent"); 8,168,209, as corrected ("the '209 patent");8,173,708 ("the '708 patent"); 8,283,379 ("the '379 patent"); 8,293,794 ("the '794 patent");8,329,752 ("the '752 patent"); 8,338,485 ("the '485 patent");

'752, '085, and '233 Patents), and for Namzaric®, Defendants listed all eleven Went Patents.) The Went Patents each name Dr. Gregory T. Went, PhD., the founder and CEO of Adamas, as the first inventor. In 2012, Adamas Pharmaceuticals entered into a commercialization and development agreement with Forest Laboratories, Inc. with respect to memantine drugs. As part of that agreement, Adamas—the original sole assignee of the Went Patents—granted Forest an exclusive license to all of the Went Patents.

59. The Went Patents are all generally directed to an extended release formulation for memantine. The patents specifically require that the plasma concentration of memantine increases at a rate that is less than half (50%) the rate for an immediate release (IR) formulation. In other words, the Went Patents are directed to a formulation that slows down systemic release of memantine compared to immediate release formulations. More specifically, the patents describe a change in plasma concentration of memantine with respect to time as "dC/dT", such that dC/dT is less than 50% that of an immediate release memantine formulation. This will be described as the "50% dC/dT limitation."

60. For example, claim 1 of one of the Went Patents, U.S. Patent No. 8,168,209 recites:

> A solid pharmaceutical composition in a unit dosage form for once daily oral administration comprising an extended release formulation of 5 to 40 mg memantine or pharmaceutically acceptable salt thereof, wherein administration of a dose of the composition to a human subject provides a plasma memantine concentration profile, as measured in a single-dose human PK study, characterized by a change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition, wherein the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine.

61. The parent patent to all the Went Patents was filed April 6, 2006 as U.S. Patent Application No. 11/399,879. The parent patent was issued as U.S. Patent 8,058,291 ("the '291 Patent") on November 15, 2011. Each of the remaining Went Patents are either continuations, continuations-in-part, or divisionals of the parent '291 Patent.

8,338,486 ("the '486 patent");8,362,085 ("the '085 patent"); 8,580,858, as corrected ("the '858 patent"); and 8,598,233 ("the '233 patent").

62. The claims of the '291 Patent are directed to extended release combinations of memantine and donepezil, the drug combination used in Namzaric®. On June 21, 2010, during prosecution of the '291 Patent application, the Examiner issued an Office Action that rejected the pending claims as anticipated over U.S. Patent Publication No. 2005/0232990 by Moebius ("Moebius"). At the time, some of the pending claims recited dissolution profiles and Tmax values, but the Examiner deemed these limitations as "inherent to the method step of administering memantine and in an extended release dosage."

63. In response to this rejection, on November 5, 2010, Dr. Went and his co-inventors amended the independent claims of the '291 Patent application to require the 50% dC/dT limitation. They argued that they were "the first to identify the link between the initial rise of memantine plasma concentration (dC/dT) and the central nervous system ("CNS") side-effects of the drug. Extended release (ER) formulations of memantine with a dC/dT below 50% of IR have been found to be well tolerated, whereas formulations with dC/dT above 80% of IR have not." In support of this argument, Dr. Went submitted a declaration dated November 5, 2010 (the "Original Went Declaration"). The declaration discussed the results of two clinical studies conducted by Adamas: ADS-DEM-C106 (the "C106 Study") and ME-110 (the "ME110 Study").

64. The C106 Study compared CNS side-effects reported by subjects from the claimed extended release formulations to immediate release formulations. The C106 Study was a single dose, non-crossover study using a cohort of 64 subjects randomized to one of four treatment arms: an immediate release memantine formulation and three extended release memantine compositions, Formulations B and C (which each satisfied the 50% dC/dT limitation) and Formulation A (which did not satisfy the 50% dC/dT limitation.)

65. In the Original Went Declaration, Dr. Went purported to describe the alleged results of the C106 Study, which evaluated the subjects in each treatment arm for purportedly known CNS side-effects of memantine. Despite the high prevalence of headaches among patients taking Formulations B and C, Dr. Went excluded headaches from his analysis. In addition, even though side-effects that were presumably not "known" to be associated with memantine were reported, they were not considered when determining the number of subjects reporting "known" side-effects. Dr.

Went stated: "[s]urprisingly, fewer subjects receiving Treatment B and C had incidences of memantine-related CNS side effects than those administered Treatment A or IR." Dr. Went also stated that the data in Table 1 shows that the extended release formulations satisfying the 50% dC/dT limitation alleviated dizziness: "there is a discernible trend that subjects treated with formulations having a memantine dC/dT greater than 50% of an IR formulation (IR and Form A ER) experienced a higher rate of occurrence of dizziness than patients treated with formulations having a memantine dC/dT less than 50% of an IR formulation (Form B ER and Form C ER)."

Table 1: CNS Side Effects

Number of Subjects with CNS Side Effects, Listed by Side Effect

	Treatment A (n=16)	Treatment B (n=16)	Treatment C (n=16)	Treatment IR(n=16)
Headache*	5 (31 %)	5 (31 %)	6 (38 %)	7 (44 %)
Dizziness*	2 (13 %)	0 (0 %)	0 (0 %)	1 (6 %)
Fatigue*	2 (13 %)	0 (0 %)	1 (6 %)	1 (6 %)
Somnolence*	0 (0 %)	0 (0 %)	0 (0 %)	1 (6 %)
Cognitive disorder*	1 (6 %)	0 (0 %)	0 (0 %)	0 (0 %)
Confusion*	0 (0 %)	0 (0 %)	0 (0 %)	1 (6 %)
Disturbance in attention*	1 (6 %)	0 (0 %)	0 (0 %)	0 (0 %)
Aggression*	1 (6 %)	0 (0 %)	0 (0 %)	0 (0 %)
Anxiety*	0 (0 %)	0 (0 %)	0 (0 %)	1 (6 %)
Migraine	0 (0 %)	1 (6 %)	0 (0 %)	0 (0 %)
Syncope Vasovagal	0 (0 %)	1 (6 %)	0 (0 %)	0 (0 %)
Hypoaesthesia	1 (6 %)	0 (0 %)	1 (6 %)	0 (0 %)
Paraesthesia	1 (6 %)	0 (0 %)	0 (0 %)	0 (0 %)
Subjects with at least one known CNS side effect of Memantine other than headache	4 (25 %)	0 (0 %)	1 (6 %)	5 (31 %)
dC/dT relative to same quantity of IR memantine	80%	40%	30%	100%

*Known Side Effects of Memantine

66. In the Original Went Declaration, Dr. Went also purported to describe the alleged results of the ME110 Study. The ME110 Study was a two period (14 days each) two-treatment crossover study without washout between treatments for 24 subjects. The study evaluated CNS side effects reported by subjects for two different formulations: (1) 10 mg, twice-a-day of immediate release formulation, and (2) 25 mg extended release formulation, dC/dT = 40% of immediate release

formulation (previously described in connection with the C106 Study as Formulation B). The Original Went Declaration did not include a table summarizing the side-effects actually reported by the subjects of the ME110 Study. Instead, Dr. Went swore in his declaration that the extended-release group experienced "no incidence" of CNS side effects (*i.e.*, 0 out of 24 subjects.) Dr. Went represented, based on disclosed data, that the extended release formulation "achieved overall higher blood plasma concentrations and memantine exposure than the" immediate release formulation. He also stated:

> Despite having been administered at a dose higher than the maximum recommended dose of memantine (20 mg/day, see Namenda® Package insert), surprisingly the once a day 25 mg ER formulation was well-tolerated with **no incidence of memantine-related CNS side effects (0 out of 24 subjects.)** This was particularly surprising to see no incidence of memantine-related CNS side effects despite having reached higher plasma concentration and AUC than that of the maximum recommended dose of IR memantine, and despite having been administered once daily rather than the recommended twice daily for the immediate release. (emphasis added.)

67. Dr. Went's summary of the reported side-effects in the ME110 Study was false. Rather than there being "no incidence" of CNS side-effects by patients taking Formulation B, in fact two out of 24 subjects in the ME110 Study who were administered the extended-release formulation (Formulation B) experienced side-effects. By contrast, only one out of 23 subjects administered the immediate-release formulation experienced side-effects. Thus, the ME110 Study showed that the extended-release formulation actually fared **worse** than the immediate-release formulation.

68. Dr. Went knew that his summary of the ME110 Study in the Original Went Declaration was false. Indeed, Dr. Went submitted the actual results of the ME110 Study to the Patent Office during prosecution of a different patent application within the same family as the Went Patents, U.S. Patent Application No. 12/757,824 ("the '824 Application"). The '824 Application was a continuation and continuation-in-part, respectively, of two earlier Went Patents, namely, the '209 Patent and the '291 Patent". At the time of filing of the '824 Application, the '209 Patent application was pending, and the '291 Patent had already been allowed.

69. During prosecution of the '824 Application, Dr. Went submitted a declaration on May 7, 2012 (the "May 7 Declaration"). At the time of this declaration, the '209 and '291 Patents had both been allowed by the Patent Office. The May 7 Declaration included a table of the actual

results from the ME110 Study. Those results showed two out of 24 subjects taking the extended-release formulation experienced side-effects, whereas only one out of 23 subjects taking the immediate-release formulation experienced side-effects. In the May 7 Declaration, Dr. Went described these results as "little incidence" of side-effects with the extended release formulation. This is in contrast to his description of the same study within the Original Went Declaration, which described the results as "no incidence" of side-effects. Set forth below is Table 2 from the May 7 Declaration, which showed the actual results of the ME110 Study.

Table 2. Subjects reporting CNS side effects in ADS-DEM-ME110 study.

Formulation	10 mg IR BID 23 subjects	25 mg ER QD 24 subjects
Headache	0	1 (1006)
Dizziness	0	1 (1006)
Anxiety	1 (1019)	1 (1019)
No. of subjects with memantine related CNS side effects	1	2
No. of subjects with memantine related CNS side effects (other than headache)	1	2

Source: ADS-DEM-ME110 CSR, table 14.3.1.5; parenthetical numbers are patient identifiers.

70. The Examiner presiding over the '824 Application was not persuaded. She stated that "the [extended release] formulation does not present better results in regards to side effects." As a result, the Examiner maintained the rejection of the pending claims. In response, Adamas abandoned the '824 Application.

71. Going back to prosecution of the '291 Patent application, after submitting the Original Went Declaration, on February 8, 2011, the Examiner once-again rejected the pending claims as obvious over Moebius in view of additional prior art. In response, on May 11, 2011, the applicants for the '291 Patent application submitted a declaration by Dr. Sid Gilman (the "Gilman Declaration").[4]

[4] Dr. Gilman has been identified as the person paid for leaking confidential information about a non-public trial of a different Alzheimer's drug to Matthew Martoma, an SAC Capital Advisors LP hedge fund manager convicted of insider trading.

72. In his declaration, Dr. Gilman swore that the inventors listed on the '291 Patent application were the first to discover that reducing dC/dT during the initial hours after administration could reduce side-effects. Dr. Gilman stated,

> In sharp difference to the teachings of Ditzler, Went et al. made the surprising discovery that the side effects of memantine were related to the initial rate of rise in memantine plasma concentration over the first several hours after dosing. Went et al. discovered that by modifying the release of memantine in a manner that slowed the initial rate of rise in plasma concentration over about 4-7 hours to a level that is less than about 50% of that of an immediate release IR memantine, the side effects of memantine could be reduced . . . . Given what was known about the pharmacokinetic and pharmacodynamics characteristics of memantine at the time of the invention, one would not have expected that extending the release of memantine plasma concentration in the first hours after administration would have had any impact at all on tolerability.

73. Shortly thereafter, on September 23, 2011, the Examiner allowed the claims based upon the alleged "unexpected results" sworn to by Dr. Went. The Examiner's reasons for allowance stated, *inter alia*, "[a]fter further consideration after a patentability conference . . . the unexpected results presented by Applicant during the course of examination overcomes the rejection of record . . . . Additionally, due to the unexpected results filed by the Applicant during the course of examination and further consideration, the previous 35 U.S.C. 103(a) rejection is also withdrawn."

74. On July 30, 2009, Dr. Went and co-inventors filed another application that eventually issued as the '209 Patent. During prosecution of the '209 Patent application, in response to Office Actions rejecting the pending claims, Dr. Went and co-inventors once again submitted the Original Went Declaration and the Gilman Declaration. Applicants also conducted a telephone interview with the Examiner that discussed the pending claims "in light of the Applicant's response and declarations in a similar application that was recently patented (11/399,879)," a reference to the '291 Patent. Defendants once again made false and misleading statements regarding the ME110 Study, and in the case of the ME110 Study, they did not provide the Examiner with the actual results of that study. The Examiner allowed the '209 Patent "[i]n light of the applicant's arguments, declarations filed December 21, 2010, demonstrating the unexpected results of the claimed composition . . . ." The '209 Patent issued on May 1, 2012.

75. On April 9, 2010, Dr. Went and co-inventors filed another application—which eventually issued as the '708 Patent—based on the '291 Patent and Dr. Went's and Dr. Gilman's misleading Declarations. During prosecution of the '708 Patent application, in response to Office Actions rejecting the pending claims, Dr. Went and co-inventors once again submitted the Original Went Declaration and the Gilman Declaration. Applicants again conducted a telephone interview with the Examiner that discussed the pending claims "in light of the Applicant's response and declarations in a similar application that was recently patented (11/399,879)," referring to the '291 Patent. Defendants once again made false and misleading statements regarding the ME110 Study, and in the case of the ME110 Study, they did not provide the Examiner with the actual results of that study. The Examiner allowed the '708 Patent "[i]n light of the applicant's arguments, declarations filed October 11, 2011, demonstrating the unexpected results of the claimed composition . . . ." The '708 Patent issued on May 8, 2012.

76. On April 9, 2010, Dr. Went and co-inventors filed another application—that would eventually issue as the '379 Patent—based on the '291 Patent and the same fraudulent Original Went Declaration and the Gilman Declaration. During prosecution of the '379 Patent application, Dr. Went and co-inventors once again submitted the Original Went Declaration and the Gilman Declaration. Applicants also conducted a telephone interview with the Examiner that discussed, as reported by Defendant's patent counsel in a summary of a prior telephone interview with the Examiner filed December 14, 2011: "the relationship between the instant application and United States Serial No. 11/399,879, which has issued as United States Patent No. 8,048,291. It was agreed that the evidence relied upon in 11/399,879 should be sufficient to obviate any obviousness rejection based on the record prior art. Accordingly, Applicants submit herewith two declarations previously made of record in 11/399,879, by Went and Gilman." This discussion also separately memorialized in an interview summary filed by the Examiner on December 20, 2011. The '379 Patent issued on October 9, 2012.

77. In connection with the '379 Patent application, Defendants once again made false and misleading statements regarding the ME110 Study, and in the case of the ME110 Study, they did not provide the Examiner with the actual results of that study. On April 3, 2012, Applicant submitted a

corrected declaration by Dr. Went of the Original Went Declaration (the "Corrected Went Declaration"). As explained in separate declarations by Dr. Went submitted on April 24, 2012 and June 15, 2012, the Corrected Went Declaration purported to correct discrepancies in the data previously presented in Table 1 of the Original Went Declaration in connection with the C106 Study. After correcting for those discrepancies, Table 1 was amended to add one subject who experienced dizziness to Treatment IR; add one subject who experienced headache to Treatment Arm A; move one subject who experienced aggression from Treatment A to Treatment Arm IR; and move one subject who experienced anxiety from Treatment IR to Treatment Arm C. Dr. Went stated that he did not "consider the noted differences to be significant," and he also stated that his "conclusions . . . did not change between filing the Original and Corrected Declarations."

78. Despite submitting the Corrected Went Declaration, and despite submitting two separate declarations to explain the Corrected Went Declaration, Defendants still did not submit the actual results of the ME110 Study or correct the prior false and misleading statements and characterizations of the ME110 Study disclosed in the Original Went Declaration.

79. Following submission of the Corrected Went Declaration, the Examiner allowed the '379 Patent. The Examiner's reasons for allowance indicated,

> The corrected declarations and applicant's arguments of record continue to demonstrate the unexpected results of the claimed method to reduce side effects that could not have been predicted by specifically reducing the plasma concentration as a function of time (dC/dT) of memantine to be less than 50% of than [*sic*] an immediate release dosage form.

80. During prosecution of the remaining Went Patents (the '752, '485, '486, '085, '858, and '233 Patents), Dr. Went submitted another version of the Original Went Declaration (signed June 25, 2012) (hereinafter, the "Third Went Declaration"). This declaration provided additional discussion of plasma memantine levels of the claimed formulations in the C106 Study. This declaration also removed prior paragraph 13 from the Original and Corrected Went Declarations, which highlighted the purported results of the C106 Study showing an alleged decreasing trend of subjects experiencing dizziness with the claimed ER formulations versus Formulation A and the IR Formulation.

81. Importantly, however, the Third Went Declaration reported the same false and misleading results of the ME110 Study and did not correct or update the prior characterization in the Original Went Declaration or the Corrected Went Declaration. Based on the stated reasons for allowance, the '752, '485, '486, '085, '858, and '233 Patents, were each allowed, like the preceding patents, based upon the purportedly "unexpected" and "surprising" results set forth in the Third Went Declaration.

82. During prosecution of the each of the Went Patents, Adamas, Dr. Went, their co-inventors, Defendants and patent-counsel for Defendants **never** disclosed to the Patent Office the actual reported side-effects of the ME110 Study. Adamas, Dr. Went, their co-inventors, Defendants and patent-counsel for Defendants **never** updated, corrected, or revised the Original Went Declaration to reflect the actual results of the ME110 Study, or to correct Dr. Went's knowing mischaracterization of the side-effects reported in the ME110 Study, especially after the Examiner's rejection of the '824 Application. Instead, based upon Original Went Declaration, the Corrected Went Declaration and the Third Went Declaration, and the false representations therein of the results of the ME110 Study, the Went Patents were each granted by the Patent Office.

83. Thus, in sum, to procure the Went Patents, Defendants told the Patent Office that the ME110 Study purportedly showed that the claimed extended release formulation had "no incidence" of side-effects. That was false. Dr. Went clearly knew this was false because in a separate, related patent application within the same family, he disclosed the actual results of the ME110 Study. Those actual results were clearly material to the patentability of the Went Patents because when the Patent Office was apprised of those results, it rejected a related patent application directed to similar subject matter, namely, an extended-release memantine formulation with purportedly superior, unexpected results. Thus, the circumstances surrounding prosecution of the Went Patents show that Dr. Went and Defendants intentionally and misleadingly withheld the actual results of the ME110 Study so that those patents would be allowed.

84. Defendant's intentional misrepresentation of the actual results of the ME110 Study was material to the patentability of the Went Patents, and the Patent Office would not have granted

the Went Patents had Defendants disclosed the actual results. Indeed, the Examiner repeatedly relied on the supposed "unexpected results" when granting each of the Went Patents.

85. In addition, the actual results of the ME110 Study (which were intentionally withheld by Defendants from the Patent Office) refute any suggestion that the results of the C106 Study, standing alone, demonstrate unexpected results. The Third Went Declaration indicated that the C106 Study included 16 patients in each treatment arm. In the C106 Study, dizziness was experienced by two subjects (13%) for Treatment A and two subjects (13%) for Treatment IR (both unclaimed formulations). By contrast, the ME110 Study included more patients for each arm: 24 patients. The actual results of the ME110 Study show that dizziness was experienced by zero subjects (0%) for Treatment IR and one subject (4.2%) for Treatment B, the extended-release formulation. Thus, in the ME110 Study, the claimed ER formulation actually fared worse for dizziness than the unclaimed instant release formulation. Similarly, in the C106 Study, anxiety was experienced by 2 subjects (13%) for Treatment A and 2 subjects (13%) for Treatment IR (both unclaimed formulations). By contrast, the actual results of the ME110 Study, which had more patients, anxiety was experienced by 1/23 subjects (4.3%) for Treatment IR, and 2/24 subjects (8.3%) for Treatment B, the extended release formulation. Thus, in the ME110 Study, the claimed XR formulation actually fared worse for anxiety than the unclaimed instant release formulation. Thus, in the ME110 Study, the claimed formulations demonstrated more CNS side-effects compared to the IR formulation. Indeed, twice the number of subjects reported CNS side-effects for the XR formulation in the ME110 Study, even though fewer categories of CNS side effects were included. Given that the ME110 Study included more statistically significant number of patients, the actual results of the ME110 Study belie any inference of unexpected results from the C106 Study.

86. Because the ME110 Study calls into question the reported results for dizziness and anxiety in the C106 Study, on information and belief, the Examiner would have likely questioned **all** results of the C106 Study. If the results of the C106 Study for both dizziness and anxiety are excluded (given that they may not show any unexpected results in light of the actual results of the ME110 Study,) then the C106 Study may show even worse results than reported.

87. Indeed, for C106 Treatment IR (one of the unclaimed formulations,) discounting headache, dizziness and anxiety, only four CNS side-effects were reported, which means the number of *subjects* reporting CNS side-effects is **at most** four (25%) and possibly lower if a subject experienced more than one CNS side-effect. That is less than the five subjects (31%) that Dr. Went stated. Therefore, the purported "unexpected results" shown in the C106 Study are not as strong as reported by Defendants during prosecution of the Went Patents.

88. Moreover, given that the Original, Corrected and Third Went Declarations only disclose the number of **subjects** who reported "known" CNS side-effects, the number of reported side effects may have in fact been greater than the number of subjects that experienced side-effects.

89. Defendants therefore failed to provide the Patent Office with sufficient detail to know if discounting headache, dizziness and anxiety would reduce the number of subjects reporting known CNS side-effects, because the required data to make that assessment (correlating reported known side-effects to specific subjects) was not disclosed in any of the Went Declarations.

90. The prosecution histories for the Went Patents also show that the Examiner relied upon the prior patentability of the parent '291 Patent in the course of allowing the subsequent Went Patents. Thus, the patentability of the Went Patents was infected by Dr. Went and Defendants' intentionally false, fraudulent and intentional conduct perpetrated in connection with the '291 Patent.

ii. The '009 Patent

91. The second category of patents listed for Namenda XR® and Namzaric® consists of U.S. Patent 8,039,009 ("the '009 Patent"). The '009 Patent was originally assigned to Forest Laboratories, Inc., and expires September 24, 2029. The '009 Patent was procured by Forest through fraud.

92. The '009 Patent is directed to a method of treating Alzheimer's disease with a once-daily sustained release oral dose of memantine. After being rejected at least six times by the Patent Office, Forest amended the application for the '009 Patent (application no. 11/155,330) to require "once daily administration." Based on this amendment, the Patent Office allowed the '009 Patent.

93. The '009 Patent was acquired by fraud. The once-daily limitation in the '009 Patent is invalid as obvious in view of U.S. Patent No. 6,479,553 ("the '553 Patent"), which expressly teaches treating Alzheimer's disease by administering memantine once daily.

94. Defendants were aware of the teachings of the '553 Patent, yet, on information and belief, Defendants intentionally failed to alert the Patent Office to the teachings of the '553 Patent when they amended the application for the '009 Patent to include the once-daily limitation. The once-daily teaching is expressly what the Examiner found lacking during the previous failed prosecution of the '009 Patent. Thus, given that the Examiner found all limitations in the claims taught within the prior art but one (the "once daily" limitation); and given that the '553 Patent expressly teaches this limitation, then the '009 Patent is *prima facie* invalid over the '553 Patent, either alone or in combination with the other art cited by the Examiner during prosecution.

95. The priority date for the '009 Patent is June 17, 2004, whereas the '553 Patent issued November 12, 2002. Thus, the '553 Patent is prior art under 35 U.S.C. § 102(b) (pre-Leahy-Smith America Invents Act ("AIA"), Public Law 112-29, codified in various sections in Title 35 of the United States Code).

96. The '553 Patent had been disclosed previously by Forest during prosecution of the '009 Patent. However, the Examiner considered the '553 Patent on September 28, 2009, at a time when the application for the '009 Patent did not suggest once-daily administration. The '553 Patent's once-daily teaching had no relevance to the application for the '009 Patent at that time, and it would not have been considered by the Examiner. It would be nearly eighteen months before Forest amended the '009 claims to require "once daily administration" on March 15, 2011.

97. On information and belief, when Forest amended the application for the '009 Patent to require once-daily administration, it intentionally declined to inform the Patent Office of the material relevance of the '553 Patent, because the '553 Patent expressly taught the very limitation added to the claims ("once daily administration") that justified allowance of the '009 Patent. Though Defendants had disclosed the '553 patent at an earlier phase of the prosecution of the '009 Patent (when the once-daily limitation disclosed by the '553 was irrelevant to the patent application), Defendants had a duty to disclose the teachings of the '553 Patent at the time they amended the '009

Patent to require once-daily administration, because the '553 Patent was material to that claim. But for this intentional concealment of the teachings of the '553 Patent, the '009 patent would not have been allowed.

98. Forest was a sophisticated pharmaceutical company with net sales in 2013 of $3.5 billion and a portfolio of more than twenty pharmaceutical products. Through its long experience with the Patent Office, Forest would have known the Examiner was unlikely to go back to a patent disclosed for a different purpose nearly eighteen months prior to see if the new once-daily limitation was taught in the '553 Patent.

99. Defendants owed a duty of candor and good faith to the Patent Office, which required them to alert the Examiner to the teachings of the '553 Patent at the time they amended the '009 claims to require "once-daily administration." "The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98." 37 C.F.R. § 1.56. Nevertheless, the regulations also specify that bad faith and intentional misconduct are not obviated simply by disclosure of a prior art reference. Section 1.56 further states, "[h]owever, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."

100. By failing to disclose the teachings of the '553 Patent at the time it amended its claims for the '009 Patent to include a once-daily administration of memantine hydrochloride, Forest failed to carry its duty of candor and good faith. Forest's omission misled the Examiner into believing the once-daily limitation was an innovation, when in fact it was explicitly taught in the prior art.

101. The '009 Patent was asserted against nine ANDA filers for generic Namenda XR®, illegally preventing their entry into the market. Significantly, the '009 Patent was not asserted against seven of the Namenda XR® ANDA filers, even though some of those generics filed Paragraph IV certifications against the '009 Patent as well. Thus, even if the '009 Patent were valid—it is not—it would not be a bar to entry for the seven ANDA filers against whom it was not asserted. Thus, but

for the Went Patents, these seven generics could have entered the market as soon as they obtained FDA approval, which they would have received much sooner.

102. The '009 Patent was asserted against all ANDA filers for Namzaric®, illegally preventing their entry into the market.

iii. The '703 Patent

103. A third category of patent, consisting of U.S. Patent No. 5,061,703 ("the '703 Patent"), was asserted by Defendants and Merz Pharma GmbH & Co. KGaA against two of the Namenda XR® ANDA filers. The '703 Patent expired on April 11, 2015, so it did not bar entry to the market for any ANDA filers for Namenda XR® after that date, and it did not affect ANDA filers in the market for Namzaric®. Only two generics filed Paragraph IV certifications for the '703 Patent. Both settled before the '703 Patent could be fully litigated.

c. Defendants Asserted the Fraudulently-Acquired Patents to Prevent Generics from Entering the Market.

i. Part I: Namenda XR®

104. Namenda XR® was approved by the FDA on June 21, 2010. The FDA granted Namenda XR® a three-year exclusivity period, plus a six-month pediatric extension, which expired on or around December 21, 2013. At least four generic drug manufacturers filed ANDAs before FDA exclusivity expired, and five more followed within a month. Eventually sixteen drug manufacturers filed ANDAs for generic versions of Namenda XR®. (*See* Table 1, *infra.*)

105. Defendants listed six of the Went Patents and the '009 and '703 Patents in the Orange Book for Namenda XR®. The '703 Patent expired on April 11, 2015. The six Went Patents were held invalid by the Federal Circuit on February 20, 2018. The following day, Amneal and Lupin launched generic versions of Namenda XR®. But for Defendants' wrongful conduct, generic manufacturers would have launched generic alternatives to Namenda XR® sooner.

106. Nine generic manufacturers had filed ANDAs by the end of January 2014, a little more than one month after FDA exclusivity expired. The ANDA filers would eventually increase to

16. Each ANDA filer submitted a Paragraph IV certification[5] stating that some or all of the Patents listed in the Orange Book for Namenda XR® were either invalid or would not be infringed by the generic versions.

107. On or around January 31, 2014, Defendants filed the first of their infringement actions against the generic manufacturers, asserting the Went Patents against all the ANDA filers. Defendants also asserted the '009 Patent against nine of the ANDA filers, and the '703 Patent against two. Filing the infringement actions triggered the automatic 30-month stay on FDA approval of the ANDAs, meaning that no generic manufacturers could enter the market before July 31, 2016.[6] The FDA approved five ANDAs within four months after expiration of the 30-month stay, and two more within a year. Defendants' Namenda XR® infringement actions. Two generic manufacturers eventually entered the market on February 21, 2018.

CHART 1 - PATENTS ASSERTED BY DEFENDANTS AGAINST NAMENDA XR® ANDA FILERS

Generic Manufacturer	ANDA Filed	ANDA Approved	Wents Asserted	'009 Asserted	'703 Asserted
Amneal Pharmaceuticals LLC	6/10/13	10/12/16	X		
Wockhardt USA LLC	12/17/13		X		X
Sun Pharmaceutical Industries, Ltd.	12/20/13	9/28/16	X	X	
Teva Pharmaceuticals USA	12/20/13		X	X	
Zydus Pharmaceuticals (USA), Inc	1/2/14	8/3/17	X		
Apotex Inc.	1/6/14	11/22/16	X	X	
Anchen Pharmaceuticals, Inc /Par	1/6/14	6/9/17	X		
Watson Laboratories, Inc.	1/27/14		X	X	
Par Pharmaceutical Inc	1/29/14		X	X	
Mylan Pharmaceuticals, Inc	3/18/14	9/28/16	X	X	X
Amerigen Pharmaceuticals, Inc	3/31/14		X	X	
Ranbaxy Laboratories Limited	5/6/14		X		
Lupin Pharmaceuticals, Inc	7/22/14	9/28/16	X		
Accord Healthcare, Inc.	8/26/15		X	X	
Panacea Biotec Ltd.	11/5/15		X		
Macleods Pharma USA, Inc.	4/19/17		X	X	

[5] *See* 21 U.S.C. §355(j)(2)(A)(vii).

[6] 21 U.S.C. §355(j)(5)(B)(iii).

108. Absent the fraudulently-obtained Went Patents and '009 Patent, the ANDA filers could have brought their generic versions of Namenda XR® to market much sooner because the 30-month stay would not have been triggered. As noted in Chart 1 above, nine generic manufacturers filed their ANDAs before the end of January 2014. Beginning on September 28, 2016, the FDA approved seven of the ANDA filers. Absent the Went Patents and the '009 Patent, these generics could have come to market immediately upon receiving FDA approval. Moreover, because there would not have been a 30-month stay on FDA approval, they would likely have been approved much more quickly.[7] As noted in Chart 1 above, the '009 Patent was not asserted against seven of the ANDA filers, so would not bar them from market entry even if it were valid (it is not).

ii. Part II: Namzaric®

Namzaric® was approved at two dosages by the FDA on December 23, 2014. The FDA apparently granted no exclusivity to Namzaric®. Generic manufacturers have been ready to enter the market since at least July 13, 2015, when first-filer Amneal submitted its ANDA, followed soon thereafter by Par, Amerigen, Accord, Apotex, and Macleods. Each of the ANDA filers submitted Paragraph IV certifications stating that Defendants' patents were either invalid or would not be infringed by the generic versions of Namzaric®.

CHART 2 - PATENTS ASSERTED BY DEFENDANTS AGAINST NAMZARIC® ANDA FILERS

Generic Manufacturer	ANDA Filed	ANDA Approved	Wents Asserted	009 Asserted[8]
Amneal	7/13/15	1/27/17	X	
Par	7/28/15		X	X
Amerigen	9/10/15		X	X
Accord	4/6/16		X	X
Apotex	9/26/16		X	X
Macleods	4/19/17		X	X

[7] Because ANDA applications are not publicly available, Plaintiffs do not know whether the ANDA filers submitted certifications regarding the '703 Patent (with the exception of Wockhardt and Mylan, who Defendants allege filed Paragraph IV certifications). Accordingly, Plaintiffs do not know if the '703 Patent prevented ANDA filers from coming to market before it expired on April 11, 2015. At the very least, the '703 Patent did not bar market entry after that date.

[8] The '703 Patent was not asserted against any of the Namzaric ANDA filers as it had already expired.

109. Defendants asserted all eleven of the fraudulently acquired Went Patents against the Namzaric® ANDA filers. This is significant because the court in the Namenda XR® infringement actions only invalidated the six Went Patents that were asserted against those ANDA filers. Though they contain substantially identical claims and were fraudulently obtained for the same reasons, the remaining five Went Patents have not been held invalid, and they continue to prevent generics from entering the market. Defendants also asserted the '009 Patent against all ANDA filers except Amneal. But for Defendants' assertion of these fraudulently-obtained patents, the generic manufacturers would have been able to enter the market beginning in January 2016 at the latest.

d. Defendants' False Claims

110. As a direct result of Defendants' fraudulent scheme, Defendants have unlawfully excluded generic manufacturers from introducing lower-priced generic alternatives for Namenda XR® and Namzaric®, allowing Defendants to charge monopoly prices. Thus, each time the Federal Government or the Plaintiff States paid for or reimbursed payments for Namenda XR® and Namzaric® while Defendants were charging monopoly prices for those drugs, they paid an illegally inflated price for those drugs. Each claim thus represents a false claim.

i. Defendants Made False Statements to The Federal and State Governments Regarding Fair And Reasonable Pricing That Was Material to The Government's Payments.

111. For a drug manufacturer to sell pharmaceutical products to the federal government—either directly through sales to a government agency, or indirectly by receiving reimbursement for sales through Medicare or Medicaid—the manufacturer must enter into several agreements with the federal government in which the manufacturer reports prices and business practices that establish the purchase price or reimbursement amounts are "fair and reasonable" under federal acquisition regulations.

112. Thus, for Defendants to sell Namenda XR® and Namzaric® to federal agencies or otherwise qualify Namenda XR® and Namzaric® for reimbursement under Medicare and Medicaid, Defendants must list Namenda XR®'s and Namzaric®'s prices on the Federal Supply Schedule (the "FSS"), a program run by the General Services Administration (the "GSA"). To do so, Defendants would have been required to sign a standard Master Agreement ("MA") and a Pharmaceutical Price

Agreement ("PPA"). *See* 38 U.S.C. § 8126 (a). The PPA must be renewed annually and include the non-federal average manufacturer price ("AMP") for the prior year. Moreover, drug manufacturers are required to update their AMP information to CMS every calendar quarter. *See* 42 C.F.R. § 414.804(a)(5). The AMP is used to calculate the Federal Ceiling Price ("FCP"), which is 76 percent of the AMP plus a discount pegged to the cost of living index. As part of this process, Defendants must periodically provide the federal government with Namenda XR®'s and Namzaric®'s commercial list price, the lowest price charged to any commercial customer (the "Most Favored Customer"), and the name and pricing information for a "Tracking Customer," which is the "customer or class of customers whose pricing is tracked against the awarded FSS pricing for the purposes of ensuring that prices remain *fair and reasonable* throughout the life of the contract." (Emphasis added.)

113. As part of the GSA's assessment of Namenda XR®'s and Namzaric®'s pricing, Defendants were required to supply a "written justification for offered pricing, a mechanism for future potential pricing adjustments, and proof that the price is fair and reasonable." *See* About GSA Schedules, available for download at, https://www.gsa.gov/acquisition/purchasing-programs/gsa-schedules/about-gsa-schedules. Defendants, however, had artificially inflated Namenda XR®'s and Namzaric®'s prices through the unlawful exclusion of generic competitors. By definition, Namenda XR®'s and Namzaric®'s pricing that Defendants supplied in connection with the FSS was *not* fair and reasonable, and Defendants' statements to the GSA were expressly false statements.

114. Drug manufacturers such as Defendants have an express obligation to provide truthful information about AMP pricing to the government, and such manufacturers may be subject to substantial penalties if they provide inaccurate AMP information. For example, the FSS Solicitation Document relating to drugs, pharmaceuticals & hematology related products provides that: "[a]ccuracy of information and computation of prices is the responsibility of the Contractor . . . . Inclusion of incorrect information will cause the Contractor to resubmit/correct and redistribute the Federal Supply Schedule Price List, and may constitute sufficient cause for Cancellation . . . and application of any other remedies as provided by law—including monetary recovery." *See*, GSA

Drugs, Pharmaceuticals & Hematology Related Products Solicitation, 01 - Solicitation Document, pp. 39-40.

115. Moreover, to receive payment or reimbursement under Medicaid or Medicare Part B for Namenda, Defendants must participate in the Medicaid Drug Rebate Program (MDRP). Under the MDRP, the manufacturer must submit product and pricing data for all of its drugs that are eligible for coverage under Medicaid to the Centers for Medicare and Medicaid Services ("CMS") *via* the Drug Data Reporting for Medicaid (DDR) system. Under the agreement, the manufacturer must supply the AMP and the number of units sold to the Department of Health and Human Services ("DHHS"). Drug manufacturers are required to provide truthful information and are subject to substantial civil penalties if they provide false information to the government. *See* 42 U.S.C. 1396r-8(b)(3)(C)(ii).

116. Defendants are also required to participate in the Section 340B Drug Pricing Program, administered by the Office of Pharmacy Affairs in the DHHS. Under this program, Defendants are required provide its drugs to eligible health care organizations and certain other entities at reduced prices based on pricing data supplied to the federal government, including with respect to the foregoing information provided to the DHHS and the GSA through the DDR and FSS, respectively.

117. Defendants' express and implied misrepresentations that its prices were fair and reasonable—and not artificially inflated through the unlawful exclusion of competitors—are *per se* material to the government's payment decision. The structure of the Medicare and Medicaid programs rely on prices that have not been manipulated through anticompetitive or otherwise wrongful actions. But for Defendants' fraudulent statements, government health programs *necessarily* would have paid less for the drugs based on generic competition.

118. Because Namenda XR® and Namzaric did not have any FDA-approved competitors—and therefore there was no "adequate price competition"—Defendants were required to provide the Government full and accurate cost or pricing data as a condition to receiving payment.

ii. Defendants Knowingly Presented, or Caused to be Presented, False or Fraudulent Claims.

119. Defendants have knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval by the United States Government and each of the States in connection with purchases of, and Medicare / Medicaid reimbursement for, Namenda XR® and Namzaric®. Defendants unlawfully acquired patents through false and misleading statements. These patents prevented generic drug manufacturers from entering the market, giving Defendants an illegally acquired and maintained monopoly on sales of Namenda XR® and Namzaric®, which Defendants exploited to raise, maintain, and stabilize artificially high prices for Namenda XR® and Namzaric®. Each and every time that Defendants submitted, or caused to be submitted, any claim for payment or reimbursement for Namenda XR® (each, a "False Claim") from the United States Government and any of the States, Defendants violated the federal False Claims Act, 31 U.S.C. §§ 3729, et seq. (the "Federal FCA"), and the state false claims act of the respective State (each, a "State FCA") in which such submission was made.

120. Each and every submission of a False Claim for Namenda XR® and Namzaric® violated the Federal FCA and the respective State FCA because, among other reasons, each False Claim was for an unlawfully elevated, maintained, or stabilized price contrary to an express or implied certification by Defendants that the price of Namenda XR® and Namzaric® reflected in each False Claim was not unlawfully elevated, maintained or stabilized in violation of applicable law, including the Sherman Act. Moreover, Defendants made false, fraudulent, and misleading statements to the Patent Office in connection with the submission of each False Claim, because, without limitation, the price of Namenda XR® and Namzaric® incorporated in each False Claim was unlawfully elevated, maintained or stabilized as a result of Defendants' false, fraudulent, and misleading statements to the Patent Office.

121. Moreover, many states require or permit pharmacists to substitute available generic unless the prescription specifically requires that that a brand drug be dispensed. Even in such states without such substitution rules, many patients would have also chosen to take a bioequivalent and less expensive generic alternative.

122. But for Defendants' misrepresentations and fraudulent conduct, approximately 90% or more of the False Claims to the United States Government and the Plaintiff States for Namenda XR® and Namzaric® would have instead been for significantly lower-priced generic alternative.

123. Each and every claim for payment or reimbursement for Namenda XR® and Namzaric® that would have been substituted for a less expensive generic equivalent also constituted a False Claim.

iii. **Defendants' Submitted or Caused to be Submitted False Claims to the Federal Government and the States.**

124. Namenda XR® and Namzaric® are covered by Medicare, Medicaid, and various federal and state government-funded health programs. Government health funds pay a significant portion of the artificially high prices for Namenda XR® and Namzaric®. Each and every claim submitted to one of these government agencies for payment or reimbursement for Namenda XR® or Namzaric® is a false claim in violation of the Federal FCA and (where applicable) a relevant State FCA, because Defendants knowingly and intentionally caused each claim to be submitted for an artificially high price that Defendants charged as a result of their fraudulently-obtained patents.

125. But for the fraudulently-acquired Went Patents, the ANDA filers for generic Namenda XR® would have been able to enter the market much sooner. Generic manufacturers were ready and willing to enter the market by December 21, 2013, when FDA exclusivity for Namenda XR® meaningfully expired: four generics had already filed ANDAs by that date, and five more would follow within the next month. Absent the Went Patents the FDA would have approved the ANDAs much more quickly, and there would have been no 30-month stay for the six ANDA filers against whom Defendants did not assert the '009 Patent.

126. Generic competition from the ANDA filers would have reduced the price of Namenda XR® by at least 90%. Defendants' illegally acquired monopoly on sales of Namenda XR® has allowed them unlawfully to set and maintain artificially inflated prices for Namenda XR®. The federal government and the Plaintiff States, through Medicare, Medicaid, and their various health services, have paid artificially inflated prices for Namenda XR® throughout the intervening time.

Because Defendants are able to charge inflated prices for Namenda XR® due to their false or misleading statements, each claim for Namenda XR® is a violation of the False Claims Act.

127. The delay caused by Defendants' manipulation of the regulatory structure for generic approval (described below) allowed Defendants to reap a windfall of hundreds of millions of dollars in Namenda XR® revenue. Much of this windfall has come at the expense of federal and state government health funds.

iv. The Federal and State False Claims Acts

128. The Federal FCA and the State FCAs provide a mechanism for the federal and state governments to protect their health care funds from such unlawful predation. Relator brings this *qui tam* action to do so.

129. As set forth below, Defendants have knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval by the United States Government and each of the Plaintiff States in connection with the sale of Namenda XR® (each, a "False Claim"). These False Claims include, without limitation: (a) claims for Medicare and Medicaid reimbursement for Namenda XR® prescriptions; and (b) claims for payment for direct purchases of Namenda XR® under certain government programs.

130. Defendants willfully made false and materially misleading statements to the Patent Office to fraudulently obtain the Went Patents. Defendants unlawfully used the Went Patents to create and extend their monopoly in the sale of Namenda XR® and exclude generic competition from the market. As a result, Defendants were able to charge artificially inflated prices for Namenda XR® and Namzaric®. Moreover, each and every claim for payment or reimbursement for Namenda XR® and Namzaric® that would have been substituted for a less expensive generic equivalent also constituted a False Claim.

131. Each and every False Claim for payment or reimbursement for Namenda XR® and Namzaric® submitted by (or caused to be submitted by) Defendants violated the Federal FCA and the respective State FCAs, because, among other reasons, each False Claim was for an unlawfully elevated, maintained, or stabilized price for Namenda XR® or Namzaric® contrary to express representations and implied certifications by Defendants to the federal government that the price of

Namenda XR® or Namzaric® reflected in each False Claim was "fair and reasonable," and not unlawfully elevated, maintained, or stabilized in violation of applicable law, including applicable antitrust laws. Despite knowing their prices were unlawfully inflated, Defendants gave the federal government and the Plaintiff States multiple express representations and implied assurances that the prices Defendants were charging for Apriso® were "fair and reasonable," which the federal government and the Plaintiff States materially relied upon when paying or reimbursing claims for Namenda XR® and Namzaric®. Moreover, Defendants made false, fraudulent, and misleading statements to the Patent Office in connection with the submission of each False Claim because the price of Namenda XR® or Namzaric® reflected in each False Claim was unlawfully elevated as a result of Defendants' false, fraudulent, and misleading statements to the Patent Office. Finally, each claim for reimbursement or payment for a prescription of Namenda XR® or Namzaric® that would have been filled by a generic alternative had Defendants not unlawfully excluded such competitors from entering the market also constituted a False Claim.

132. According to CMS, for the years 2014 and 2015 (the last year for which figures are available), Medicare reimbursed approximately 5,408,646 prescriptions for Namenda XR® for approximately $1.46 billion. Allergan's 2017 Form 10-K states that United States net revenues for Namenda XR® decreased by approximately 17% in 2016, and 28% in 2017. Applying those percentages to Medicare's total 2015 spending for Namenda XR® of $951,940,769, it is reasonable to estimate that Medicare spent approximately $790,110,838 on Namenda XR® in 2016 and $568,879,803 in 2017. That would bring estimated total Medicare spending for the years 2014-2017 to $2,822,366,776.

133. Studies have shown that when multiple generics enter the market for a given drug, prices decrease by 90% or more. Indeed, Allergan's 2016 Form 10-K states that this is precisely what happened when the immediate release version of Namenda®—Namenda® IR—lost its patent exclusivity: "The decrease in the US General Medicine segment revenues is primarily driven by the loss of exclusivity on Namenda® IR, which declined $541.2 million, or 97.3%, versus the prior year period." (emphasis added).

134. But for Defendants' unlawful exclusion of competitors from introducing generic alternatives in 2014, the cost to government-funded health care programs would have been reduced by at least 90%.

135. Under the False Claims Act, damages are trebled, which would bring the damages total to an estimated $7,620,390,295. Additionally, under the False Claims Act, the United States is entitled to a maximum penalty of up to $22,363 for each and every violation alleged herein.

136. Namenda XR® and Namzaric® are also covered by Medicaid programs for all Plaintiff States, making payments relating to Namenda XR® and Namzaric® purchases and reimbursements a substantial burden on Medicaid funds. Between 2013 (the first year in which Medicaid paid for Namenda XR®) and 2016 (the last year for which Medicaid statistics are available), Medicaid reimbursed 107,899 claims for Namenda XR® for approximately $ 30.6 million. In 2015 and 2016 (the first and last years statistics are available), Medicaid reimbursed 2,105 claims for Namzaric® for $ 622,749. While sales in the United States for Namenda fell by thirty percent in 2017, they were still substantial, at $452.8 million. And United States sales of Namzaric more than doubled to $130.8 million in 2017. So it is safe to assume that Medicare and Medicaid payments continued at substantial levels in 2017 and 2018.

137. The United States Government also purchases Namenda XR® through government-funded health programs, including, without limitation, CHIP; the Indian Health Service; the Federal Bureau of Prisons' Health Services Division; the Veterans Health Administration; the Military Health System; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Defense Health Agency / TRICARE; and the Coast Guard's Office of Health Services.

138. Each and every time that Defendants submitted, or caused to be submitted, any False Claim for payment or reimbursement for Namenda XR® and Namzaric® to the United States Government or any of the Plaintiff States, Defendants violated the federal False Claims Act, 31 U.S.C. §§ 3729–, and the state false claims act of the respective Plaintiff State in which such submission was made, as applicable.

139. As set forth herein, Defendants' actions alleged in this Complaint violate the Federal FCA and the following State FCAs: The California False Claims Act, Cal. Gov't Code §§ 12650–

12656; Colorado Medicaid False Claims Act, Colo. Rev. Stat §§ 25.5-4-303.5 to -310; Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274 to -289; Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201-1211; District of Columbia False Claims Act, D.C. Code §§ 2-381.01 to .09; Florida False Claims Act, Fla. Stat. §§ 68.081–.09; Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 to 168.6; Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 to -31; Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1–175/8; Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 to -18; Iowa False Claims Act, Iowa Code §§ 685.1–.7; Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437–:440; Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 to -611; Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A–5O; Michigan Medicaid False Claims Act, Mich. Comp. Laws. §§ 400.601–.615; Minnesota False Claims Act, Minn. Stat, §§ 15C.01–.16; Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 to -413; Nevada statute concerning Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010–.250; New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 to -18; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15, and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14; New York False Claims Act, N.Y. State Fin. Law §§ 187–194; North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 to -618; Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053–5053.7; Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9; Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 to -185; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001–.132; Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630–642; Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 to .19; and Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005–.130.

v. Defendants Wrongfully Blocked Generic Competition

140. When the FDA approved Defendants' NDA for Namenda XR® on June 21, 2010, it granted Defendants a three-year New Dosage Form exclusivity period plus a 6-month pediatric extension, which ended on or about December 21, 2013. If the Went Patents had been upheld, Defendants would have held a monopoly on sales of Namenda XR® until at least May 22, 2026.

141. Several generic manufacturers were ready to enter the market when Defendants' FDA-granted exclusivity expired in 2013. Indeed, four generic manufacturers (Amneal, Teva, Wockhardt, and Sun) had already submitted their ANDAs before the FDA-approved exclusivity expired, and eight more followed within the next five months (Apotex, Zydus, Anchen, Par, Watson, Amerigen, Mylan, and Ranbaxy). Beginning on January 31, 2014, Defendants filed infringement actions against all the ANDA filers, which automatically triggered a 30-month stay on FDA approval of the ANDAs. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

142. The FDA approved three ANDAs (Lupin, Mylan, and Sun) for extended release memantine within two months after the expiration on or about July 31, 2016, of the 30-month stay. Four more ANDAs were approved soon thereafter (Amneal, Anchen, Apotex, and Zydus). However, the ANDA filers were still prevented from entering the market by the fraudulently-obtained Went Patents and '009 Patent. On July 27, 2016, the United States District Court for the District of Columbia ruled that all six of the Went Patents listed in the Orange Book for Namenda XR® were invalid. The Federal Circuit issued its final ruling upholding the district court decision on February 20, 2018. The very next day, Amneal and Lupin released generic equivalents of Namenda XR®.

143. Defendants' listing of the Went Patents and the '009 Patent in the Orange Book constituted a false and fraudulent statement to the U.S. government.

144. Because Defendants fraudulently obtained the Went Patents and improperly listed them in the Orange Book, Defendants forced the ANDA Filers to file Paragraph IV certifications. Defendants instituted objectively baseless litigation against the ANDA Filers, alleging infringement of Defendants' invalid, unenforceable, and fraudulently-obtained Went Patents and '009 Patent. By filing the infringement lawsuits, Defendants triggered the 30-month stay on FDA approval of each of the ANDA Filers' applications to market generic alternatives to Namenda XR®. Defendants commenced these sham litigations for the anticompetitive and unlawful purpose of delaying or preventing generic entry into the relevant market.

145. Additionally, by appealing the district court's decision invalidating the Went Patents, Defendants ensured that no generic could enter the market for another year—until those appeals were

finally resolved on February 20, 2018. In this way, Defendants unlawfully but successfully blocked generics from entering the market from approximately December 21, 2013, to February 20, 2018.

146. Because of Defendants' false and misleading statements to the Patent Office in procuring the Went Patents and the '009 Patent, the Federal Government and the Plaintiff States have been deprived of a lower-cost generic form of Namenda XR® for more than five years. The Federal Government and the Plaintiff States continue to overpay for Namenda XR® to this day, even though two generics have entered the market. Studies have shown that prices continue to drop as more generic manufacturers enter the market for a given drug, up to as many as twenty manufacturers. Even after two generics have entered the market, prices can continue to drop.

147. The federal government and Plaintiff States are also continuing to overpay for Namzaric®, for which Defendants still hold a complete monopoly based solely on their fraudulently-acquired patents. Defendants have settled all infringement actions related to Namzaric®, removing the current possibility that a federal court will invalidate the remaining Went Patents or the '009 Patent. Thus, the federal government and the Plaintiff States could conceivably continue to overpay until the last of the patents expires in 2029.

vi. Defendants' Fraudulent Scheme Has Resulted in Thousands of False Claims

148. Defendants initiated the fraudulent scheme alleged herein to allow them to continue selling Namenda XR® at monopoly prices after the expiration of the FDA exclusivity period. Defendants knew and intended to unlawfully sell Namenda XR® at monopoly prices during the 30-month stay and the pendency of the Hatch-Waxman litigations Defendants' initiated against the ANDA filers.

149. Defendants' fraudulent scheme erected significant barriers to the introduction of generic alternatives to Namenda XR® in interstate commerce and constitutes a willful attempt to retain monopoly power over the relevant market. Defendants' wrongful conduct has restrained competition in violation of federal and state antitrust laws, enabling Defendants to charge the United States Government and the Plaintiff States illegally-inflated prices for Namenda XR® and Namzaric®.

150. Defendants have used their illegal monopoly to overcharge the United States Government and the Plaintiff States for Namenda XR® and Namzaric®.

151. Defendants knew that the United States and the Plaintiff States would be purchasers and third-party payers for Namenda XR® through direct or indirect sales of Namenda XR® or the payment of claims for prescription drug reimbursement submitted by providers under government programs, including Medicare and Medicaid.

152. Defendants knew that they would be submitting claims to the United States and the Plaintiff States and causing or inducing others to submit claims based on Defendants' illegally-inflated pricing for Namenda XR® and Namzaric®. Defendants were also well-aware of the statutory structures that govern the methods by which the United States and the Plaintiff States reimbursed outpatient drugs covered under Medicare and Medicaid.

153. Defendants, their employees and agents, individually and in concert, knowingly submitted or caused to be submitted false claims to the United States Government and the Plaintiff States to secure payments for illegally-inflated prices for Namenda XR® and Namzaric®.

154. The United States Government and the Plaintiff States were unaware of Defendants' fraudulent scheme, misrepresentations to the Patent Office, and wrongful listing of the Went Patents in the Orange Book at the time they paid False Claims.

155. Defendants' misrepresentations and fraudulent course of conduct were material to the United States Government and the Plaintiff States paying the False Claims. In purchasing drugs or reimbursing for prescriptions as an end-payor, the United States Government and the Plaintiff States require that the prices they pay or the amounts they reimburse have not been manipulated, inflated or maintained through the wrongful suppression of competition or other wrongful conduct.

a. Because Namenda XR® did not have any FDA-approved competitors—and therefore there was no "adequate price competition"—Defendants were required to provide the Government full and accurate cost or pricing data as a condition to receiving payment.

b. Defendants' disclosure was required because the Government may pay only a "fair and reasonable" price for pharmaceuticals.

c. As part of its required disclosure, Defendants were obligated to include all facts that a prudent buyer or seller would reasonably expect to affect prices—such as whether the prices have been inflated through anticompetitive conduct.

d. Upon information and belief, Defendants certified that the cost or pricing data they provided to the Government was "accurate, complete and current." Contrary to their certification, however, Defendants failed to disclose to the Government that the prices they were charging for Namenda XR® were monopoly prices based on Defendants' fraudulent exclusion of generic competition. Because the Government may pay only a "fair and reasonable price" for pharmaceuticals based on "accurate, complete and current" cost or pricing data, Defendants' misrepresentations and fraudulent conduct were material to the Government's payments of the False Claims alleged herein. Had the Government or the Plaintiff States known about Defendants' misrepresentations and fraudulent scheme to obtain the Went Patents to block generic competition for Namenda XR®, the Government and the Plaintiff States would not have paid or reimbursed for Namenda XR® at Defendants' monopoly prices.

e. Reimbursements under the Medicare framework assume that a drug's price has not been wrongfully inflated or maintained through anticompetitive conduct or the wrongful exclusion of competitors. CMS requires drug manufacturers (such as Defendants) to provide it with accurate manufacturer prices for compilation in CMS's Average Manufacturer Price ("AMP") and Average Selling Price ("ASP") database files. CMS uses their AMP and ASP calculations to set certain price limits and reimbursement levels for pharmaceutical products under the Medicare and Medicaid program. An integral assumption in CMS's reimbursement decisions is that pharmaceutical prices reflect competitive market prices that have not been unlawfully inflated or maintained through anticompetitive conduct or the wrongful exclusion of competitors. Therefore, Defendants' misleading statements and fraudulent conduct are necessarily material to the Government's payments of the False Claims alleged herein.

f. CMS calculates Medicare reimbursement rates for certain outpatient drugs based on a percentage ASP. For drugs with therapeutic equivalents, CMS is required to weigh the calculation of ASPs based on drug utilization (or volume of sales). Because of the number of generic

competitors that would have entered the market in September 2014, generic versions of Namenda XR® would have quickly captured at least 90% of the market. Therefore, CMS's ASP calculations would have been heavily weighted towards the average lower generic selling prices.

g. CMS calculates every month a "Federal Upper Limit" for Medicaid reimbursements of covered pharmaceuticals based on a percentage of the AMP. The AMP calculation must include the prices of pharmaceutically and therapeutically equivalent generic alternatives and be weighted towards those drugs with the highest utilization or *volume* of sales. Because of the number of generic competitors that would have entered the market when the FDA-approved exclusivity period ended in or around December 2013, generic versions of Namenda XR® would have quickly captured at least 90% of the market, and the Federal Upper Limit for Namenda XR® prescriptions would have been heavily weighted towards the average lower generic selling prices. Therefore, Defendants' misrepresentations and fraudulent conduct were *necessarily* material to the Government's and Plaintiff States' payments of the False Claims because they would have been statutory *prohibited* from paying the higher amount requested in the False Claims.

156. Defendants' misrepresentations and fraudulent conduct allowed Defendants to bill (or cause the submission to and payment of reimbursement claims by) the United States Government and the Plaintiff States for a higher priced good (*i.e.,* a patented drug with no generic competitors) than what was actually provided (a non-patented drug that should have had numerous generic competitors). On information and belief, the United States Government and the Plaintiff States paid or reimbursed for Namenda XR® at Defendants' unlawfully inflated monopoly prices, but they would not have entered into such contracts or paid such amounts had they known the true facts at the time of contracting or payment. The United States Government and the Plaintiff States would not have accepted or made payments on invoices for patented Namenda XR® or Namzaric® but for the fraudulently-obtained Went Patents.

157. But for Defendants' misrepresentations and fraudulent conduct, approximately 90% or more of the False Claims to the United States Government and the Plaintiff States for Namenda XR® and Namzaric® would have instead been for significantly lower-priced generic versions of the drugs.

158. Each and every claim for payment or reimbursement for Namenda XR® or Namzaric® that would have been substituted for a less expensive generic equivalent also constituted a False Claim.

159. Using its fraudulently-obtained patent rights, Defendants have submitted or caused to be submitted thousands of False Claims to the United States Government and the Plaintiff States, either through direct sales of Namenda XR® and Namzaric® or False Claims for reimbursement for Namenda XR® and Namzaric® submitted to the Medicare and Medicaid programs. Defendants submitted the False Claims or caused the False Claims to be submitted to the United States Government and the Plaintiff States based on unlawful pricing above the what the fair market value of Namenda XR® and Namzaric® would have been but for Defendants' unlawful and fraudulent blocking of generic entry.

160. Defendants submitted or caused submission of False Claims with false certifications of compliance with law. The United States Government and the Plaintiff States conditioned payment or reimbursement for Namenda XR® and Namzaric® upon these false certifications. Unaware of Defendants' fraudulent scheme, the United States Government and the Plaintiff States issued payment on those False Claims.

VII. CLAIMS FOR RELIEF

Claim for Relief I
False Claims Act
31 U.S.C. §§ 3729–3733

161. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

162. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729–3733, as amended.

163. Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment of Namenda XR® and Namzaric®.

164. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the

United States. Relator has no control over, or dealings with, such entities, and has no access to the records in their possession.

165. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the Government would not have paid but for Defendants' illegal conduct.

166. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

167. Additionally, the United States is entitled to a maximum penalty of up to $22,363 for each and every violation alleged herein.

Claim for Relief II
California False Claims Act
Cal. Gov't Code §§ 12650–12656

168. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

169. This is a claim for treble damages and penalties under the California False Claims Act.

170. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

171. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

172. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® .Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of California—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

173. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of California.

174. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of California. Relator has no control over or dealings with such entities and has no access to the records in their possession.

175. The State of California, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of California would not have paid but for Defendants' illegal conduct.

176. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

177. Additionally, the State of California is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

178. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of California pursuant to Cal. Gov't Code § 12652(c)(1).

Claim for Relief III
Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-303.5 to -310

179. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

180. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

181. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR®.

182. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

183. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or

statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

184. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Colorado—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

185. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Colorado.

186. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Colorado. Relator has no control over or dealings with such entities and has no access to the records in their possession.

187. The State of Colorado, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Connecticut would not have paid but for Defendants' illegal conduct.

188. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

189. Additionally, the State of Colorado is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

190. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Colorado pursuant to Colo. Rev. Stat § 25.5-4-306(2).

Claim for Relief IV
Connecticut False Claims Act
Conn. Gen. Stat. §§ 4-274 to -289

191. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

192. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

193. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

194. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

195. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

196. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Connecticut—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

197. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Connecticut.

198. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Connecticut. Relator has no control over or dealings with such entities and has no access to the records in their possession.

199. The State of Connecticut, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Connecticut would not have paid but for Defendants' illegal conduct.

200. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

201. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Connecticut pursuant to Conn. Gen. Stat. § 4-277(a).

Claim for Relief V
Delaware False Claims and Reporting Act
Del. Code Ann. tit. 6, §§ 1201-1211

202. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

203. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

204. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

205. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

206. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

207. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Delaware —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

208. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Delaware.

209. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Delaware. Relator has no control over or dealings with such entities and has no access to the records in their possession.

210. The State of Delaware, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Delaware would not have paid but for Defendants' illegal conduct.

211. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

212. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Delaware pursuant to Del. Code Ann. tit. 6, § 1203(b)(1).

Claim for Relief VI
Florida False Claims Act
Fla. Stat. §§ 68.081–.09

213. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

214. This is a claim for treble damages and penalties under the Florida False Claims Act.

215. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

216. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

217. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

218. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Florida —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

219. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Florida.

220. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Florida. Relator has no control over or dealings with such entities and has no access to the records in their possession.

221. The State of Florida, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Florida would not have paid but for Defendants' illegal conduct.

222. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

223. Additionally, the State of Florida is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

224. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Florida pursuant to Fla. Stat. § 68.083(2).

Claim for Relief VII
Georgia False Medicaid Claims Act
Ga. Code Ann. §§ 49-4-168 to -168.6

225. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

226. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

227. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

228. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

229. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

230. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Georgia —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

231. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Georgia.

232. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Georgia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

233. The State of Georgia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Georgia would not have paid but for Defendants' illegal conduct.

234. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

235. Additionally, the State of Georgia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

236. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Georgia pursuant to Ga. Code Ann. §49-4-168.2(b).

Claim for Relief VIII
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21 to -31

237. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

238. This is a claim for treble damages and penalties under Hawaii False Claims Act.

239. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

240. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

241. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or

statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

242. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Hawaii —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

243. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Hawaii.

244. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Hawaii. Relator has no control over or dealings with such entities and has no access to the records in their possession.

245. The State of Georgia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Hawaii would not have paid but for Defendants' illegal conduct.

246. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

247. Additionally, the State of Hawaii is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

248. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Hawaii pursuant to Haw. Rev. Stat. § 661-25(a).

Claim for Relief IX
Illinois False Claims Act
740 Ill. Comp. Stat. 175/1–175/8

249. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

250. This is a claim for treble damages and penalties under the Illinois False Claims Act.

251. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

252. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

253. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

254. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Illinois —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

255. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Illinois.

256. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Illinois. Relator has no control over or dealings with such entities and has no access to the records in their possession.

257. The State of Illinois, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Illinois would not have paid but for Defendants' illegal conduct.

258. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

259. Additionally, the State of Illinois is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

260. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Illinois pursuant to 740 Ill. Comp. Stat. 175/4(b)(1).

Claim for Relief X
Indiana False Claims and Whistleblower Protection Act
Ind. Code §§ 5-11-5.5-1 to -18

261. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

262. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

263. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

264. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

265. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

266. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Indiana —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

267. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Indiana.

268. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Indiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

269. The State of Indiana, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Indiana would not have paid but for Defendants' illegal conduct.

270. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

271. Additionally, the State of Indiana is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

272. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Indiana pursuant to Ind. Code § 5-11-5.5-4(a).

Claim for Relief XI
Iowa False Claims Act
Iowa Code §§ 685.1–.7

273. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

274. This is a claim for treble damages and penalties under the Iowa False Claims Act.

275. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

276. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

277. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

278. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Iowa —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

279. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Iowa.

280. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the

State of Iowa. Relator has no control over or dealings with such entities and has no access to the records in their possession.

281. The State of Iowa, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Iowa would not have paid but for Defendants' illegal conduct.

282. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

283. Additionally, the State of Iowa is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

284. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Iowa pursuant to Iowa Code § 685.3(2)(a).

Claim for Relief XII
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. §§ 46:437–:440

285. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

286. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

287. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

288. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

289. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

290. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Louisiana —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

291. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Louisiana.

292. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Louisiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

293. The State of Louisiana, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Louisiana would not have paid but for Defendants' illegal conduct.

294. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

295. Additionally, the State of Louisiana is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

296. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Louisiana pursuant to La. Rev. Stat. Ann. § 46:439.1.

Claim for Relief XIII
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. §§ 2-601 to -611

297. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

298. This is a claim for treble damages and penalties under the Maryland False Health Claims Act.

299. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

300. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

301. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

302. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Maryland —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

303. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Maryland.

304. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Maryland. Relator has no control over or dealings with such entities and has no access to the records in their possession.

305. The State of Maryland, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Maryland would not have paid but for Defendants' illegal conduct.

306. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

307. Additionally, the State of Maryland is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

308. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Maryland pursuant to Md. Code Ann., Health-Gen. § 2-604(a)(1).

Claim for Relief XIV
Massachusetts False Claims Act
Mass. Gen. Laws ch. 12, §§ 5A–5O

309. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

310. This is a claim for treble damages and penalties under the Massachusetts False Claims Act.

311. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

312. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

313. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

314. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the Commonwealth of Massachusetts —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

315. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Commonwealth of Massachusetts.

316. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the Commonwealth of Massachusetts. Relator has no control over or dealings with such entities and has no access to the records in their possession.

317. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the

claims that the Commonwealth of Massachusetts would not have paid but for Defendants' illegal conduct.

318. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

319. Additionally, the Commonwealth of Massachusetts is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

320. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the Commonwealth of Massachusetts pursuant to Mass. Gen. Laws. ch. 12, § 5C(2).

Claim for Relief XV
Michigan Medicaid False Claims Act
Mich. Comp. Laws §§ 400.601-.615

321. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

322. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

323. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

324. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

325. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

326. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Michigan —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

327. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Michigan.

328. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Michigan. Relator has no control over or dealings with such entities and has no access to the records in their possession.

329. The State of Michigan, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Michigan would not have paid but for Defendants' illegal conduct.

330. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

331. Additionally, the State of Michigan is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

332. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Michigan pursuant to Mich. Comp. Laws § 400.610a(1).

Claim for Relief XVI
Minnesota False Claims Act
Minn. Stat. §§ 15C.01–.16

333. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

334. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

335. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

336. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

337. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

338. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Minnesota —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

339. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Minnesota.

340. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Minnesota. Relator has no control over or dealings with such entities and has no access to the records in their possession.

341. The State of Minnesota, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Minnesota would not have paid but for Defendants' illegal conduct.

342. By reason of Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

343. Additionally, the State of Minnesota is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

344. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Minnesota pursuant to Minn. Stat. § 15C.05.

Claim for Relief XVII
Montana False Claims Act
Mont. Code Ann. §§ 17-8-401 to -413

345. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

346. This is a claim for treble damages and penalties under the Montana False Claims Act.

347. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

348. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

349. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

350. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Montana —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

351. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Montana.

352. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Montana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

353. The State of Montana, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Montana would not have paid but for Defendants' illegal conduct.

354. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

355. Additionally, the State of Montana is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

356. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Montana pursuant to Mont. Code Ann. § 17-8-406(1).

Claim for Relief XVIII
Nevada Submission of False Claims to State or Local Government
Nev. Rev. Stat. §§ 357.010–.250

357. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

358. This is a claim for treble damages and penalties under the Nevada statute relating to the Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010–.250

359. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

360. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

361. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

362. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Nevada —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

363. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Nevada.

364. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Nevada. Relator has no control over or dealings with such entities and has no access to the records in their possession.

365. The State of Nevada, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Nevada would not have paid but for Defendants' illegal conduct.

366. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

367. Additionally, the State of Nevada is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

368. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Nevada pursuant to Nev. Rev. Stat. § 357.080.

Claim for Relief XVIX
New Jersey False Claims Act
N.J. Stat. Ann. §§ 2A:32C-1 to -18

369. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

370. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

371. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

372. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

373. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

374. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of New Jersey —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

375. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New Jersey.

376. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of New Jersey. Relator has no control over or dealings with such entities and has no access to the records in their possession.

377. The State of New Jersey, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of New Jersey would not have paid but for Defendants' illegal conduct.

378. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

379. Additionally, the State of New Jersey is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

380. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New Jersey pursuant to N.J. Stat. Ann. § 2A:32C-5(b).

Claim for Relief XX
New Mexico Medicaid False Claims
N.M. Stat. Ann. §§ 27-14-1 to -15

381. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

382. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

383. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

384. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

385. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or

statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

386. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of New Mexico—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

387. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New Mexico.

388. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of New Mexico. Relator has no control over or dealings with such entities and has no access to the records in their possession.

389. The State of New Mexico, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of New Mexico would not have paid but for Defendants' illegal conduct.

390. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

391. Additionally, the State of New Mexico is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

392. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New Mexico pursuant to N.M. Stat. Ann. § 27-14-7.

Claim for Relief XXI
New Mexico Fraud Against Taxpayers Act
N.M. Stat. Ann. §§ 44-9-1 to -14

393. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

394. This is a claim for treble damages and penalties under the New Mexico Fraud Against Taxpayers Act.

395. Through the acts described herein, Defendants knowingly, intentionally, and willfully violated the New Mexico Fraud Against Taxpayers Act.

396. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New Mexico pursuant to N.M. Stat. Ann. § 44-9-5.

Claim for Relief XXII
New York False Claims Act
N.Y. State Fin. Law §§ 187–194

397. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

398. This is a claim for treble damages and penalties under the New York False Claims Act.

399. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

400. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

401. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

402. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of New York—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

403. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New York.

404. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of New York. Relator has no control over or dealings with such entities and has no access to the records in their possession.

405. The State of New York, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of New York would not have paid but for Defendants' illegal conduct.

406. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

407. Additionally, the State of New York is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

408. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of New York pursuant to N.Y. State Fin. Law § 190(2)(a).

Claim for Relief XXIII
North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-605 to -618

409. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

410. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

411. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

412. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

413. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

414. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of North Carolina—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

415. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of North Carolina.

416. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of North Carolina. Relator has no control over or dealings with such entities and has no access to the records in their possession.

417. The State North Carolina, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of North Carolina would not have paid but for Defendants' illegal conduct.

418. By reason of Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

419. Additionally, the State of North Carolina is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

420. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of North Carolina pursuant to N.C. Gen. Stat. § 1-608(b).

Claim for Relief XXIV
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63, §§ 5053–5053.7

421. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

422. This is a claim for treble damages and penalties under the Oklahoma False Claims Act.

423. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

424. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

425. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

426. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Oklahoma—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

427. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Oklahoma.

428. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Oklahoma. Relator has no control over or dealings with such entities and has no access to the records in their possession.

429. The State of Oklahoma, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Oklahoma would not have paid but for Defendants' illegal conduct.

430. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

431. Additionally, the State of Oklahoma is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

432. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Oklahoma pursuant to Okla. Stat. tit. 63, § 5053.2(B)(1).

Claim for Relief XXV
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1-1 to -9

433. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

434. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

435. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

436. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

437. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

438. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Rhode Island —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

439. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Rhode Island.

440. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Rhode Island. Relator has no control over or dealings with such entities and has no access to the records in their possession.

441. The State of Rhode Island, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Rhode Island would not have paid but for Defendants' illegal conduct.

442. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

443. Additionally, the State of Rhode Island is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

444. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Rhode Island pursuant to R.I. Gen. Laws § 9-1.1-4(b).

Claim for Relief XXVI
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 7-5-181 to -185

445. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

446. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

447. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

448. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

449. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

450. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Tennessee—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

451. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Tennessee.

452. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Tennessee. Relator has no control over or dealings with such entities and has no access to the records in their possession.

453. The State of Tennessee, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Tennessee would not have paid but for Defendants' illegal conduct.

454. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

455. Additionally, the State of Tennessee is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

456. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Tennessee pursuant to Tenn. Code Ann. § 71-5-183(b)(1).

Claim for Relief XXVII
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §§ 36.001–.132

457. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

458. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

459. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

460. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

461. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

462. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Texas—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

463. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Texas.

464. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Texas. Relator has no control over or dealings with such entities and has no access to the records in their possession.

465. The State of Texas, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Texas would not have paid but for Defendants' illegal conduct.

466. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

467. Additionally, the State of Texas is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

468. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Texas pursuant to Tex. Hum. Res. Code Ann. § 36.101.

Claim for Relief XXVIII
Vermont False Claims Act
Vt. Stat. Ann. tit. 32, §§ 630–642

469. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

470. This is a claim for treble damages and penalties under the Vermont False Claims Act.

471. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

472. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

473. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or

statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

474. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Vermont —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

475. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Vermont.

476. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Vermont. Relator has no control over or dealings with such entities and has no access to the records in their possession.

477. The State of Vermont, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Vermont would not have paid but for Defendants' illegal conduct.

478. By reason of Defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

479. Additionally, the State of Vermont is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

480. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Vermont pursuant to Vt. Stat. Ann. tit. 32, § 632(b)(1).

Claim for Relief XXIX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.1 to .19

481. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

482. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

483. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

484. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

485. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

486. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the Commonwealth of Virginia—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

487. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Commonwealth of Virginia.

488. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the Commonwealth of Virginia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

489. The Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the Commonwealth of Virginia would not have paid but for Defendants' illegal conduct.

490. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

491. Additionally, the Commonwealth of Virginia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

492. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the Commonwealth of Virginia pursuant to Va. Code Ann. § 8.01-216.5(A).

Claim for Relief XXX
Washington State Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.005–.130

493. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

494. This is a claim for treble damages and penalties under the Washington State Medicaid Fraud False Claims Act.

495. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

496. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

497. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

498. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Washington—through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

499. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Washington.

500. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Washington. Relator has no control over or dealings with such entities and has no access to the records in their possession.

501. The State of Washington, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Washington would not have paid but for Defendants' illegal conduct.

502. By reason of Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

503. Additionally, the State of Washington is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

504. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Washington pursuant to Wash. Rev. Code § 74.66.050.

Claim for Relief XXXI
The District of Columbia False Claims Law
D.C. Code §§ 2-381.01 to .09

505. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

506. This is a claim for treble damages and penalties under the District of Columbia False Claims Law.

507. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Namenda XR® and Namzaric®.

508. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

509. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Namenda XR® and Namzaric®.

510. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the District of Columbia —through any state funded program, including, without limitation, Medicaid—for Namenda XR® and Namzaric®.

511. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the District of Columbia.

512. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the District of Columbia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

513. The District of Columbia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that District of Columbia would not have paid but for Defendants' illegal conduct.

514. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

515. Additionally, the District of Columbia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

516. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the District of Columbia pursuant to D.C. Code § 2-381.03(b)(1).

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

517. That Defendants cease and desist from violating 31 U.S.C. §§ 3729–3733, and the relevant parts of each statute applicable to the Plaintiff States as set forth above;

518. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $22,363 for each violation of 31 U.S.C. §§ 3729–3733;

519. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the California False Claims Act, Cal. Gov't Code §§ 12650–12656;

520. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat §§ 25.5-4-303.5 to -310;

521. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274 to -289;

522. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201–1211;

523. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Florida False Claims Act, Fla. Stat. §§ 68.081–.09;

524. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 to -168.6;

525. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 to -31;

526. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1–175/8;

527. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 to -18;

528. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of Iowa False Claims Act, Iowa Code §§ 685.1–.7;

529. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437–:440;

530. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 to -611;

531. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages Commonwealth of Massachusetts has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A–5O;

532. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Michigan Medicaid False Claims Act, Mich. Comp. Laws. §§ 400.601–.615;

533. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Minnesota False Claims Act, Minn. Stat, §§ 15C.01–.16;

534. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 to -413;

535. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Nevada statute concerning Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010–.250;

536. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 to -18;

537. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15; and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14.

538. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the New York False Claims Act, N.Y. State Fin. Law §§ 187–194;

539. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 to -618;

540. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a

civil penalty for the maximum amount allowed by statute, for each violation of the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053–5053.7;

541. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9;

542. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 to -185;

543. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001–.132;

544. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Vermont has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630–642;

545. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 to .19;

546. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005–.130;

547. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a

civil penalty for the maximum amount allowed by statute, for each violation of the District of Columbia False Claims Act, D.C. Code §§ 2-381.01 to .09;

548. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), and the relevant provisions of each statute applicable to the Plaintiff States as set forth above;

549. That Relator be awarded all costs of this action;

550. That the Relator be awarded reasonable attorneys' fees; and

551. That Relator recover such further and other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: January 22, 2019

By: */s/ Joseph R. Saveri*
Joseph R. Saveri

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United States of America; the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington; the Commonwealths of Massachusetts and Virginia; and the District of Columbia, *ex rel.* Zachary Silbersher